



## PRODUCT DATA

# Medical Grade Compounds

Precision Associates manufactures a number of compounds that are suitable for use in medical applications requiring body or body fluid contact. These materials have been tested by independent laboratories and/or our material suppliers to assess their ability to meet requirements as defined by several standards organizations. The definitions of our medical grades are listed below. PAI compounds that meet these requirements are outlined on the back of this document.

### USP VI / ISO 10993 Grade

The United States Pharmacopeia (USP) is an official public standards setting authority for medicines and other health care products manufactured or sold in the United States. PAI rubber compounds have been tested to meet USP <87> and <88> Biological Reactivity Tests for Class VI materials and USP <661> Physicochemical Tests for plastics. ISO 10993 is a 20 part series of biological evaluations used to confirm suitability in Medical Devices (see below). Additionally, PAI USP VI / ISO 10993 compounds are formulated with materials sanctioned under the FDA Code of Federal Regulations, Title 21, Part 177.2600. Each lot undergoes physical property testing.

Precision Associates recommends the use of the above materials in medical devices requiring contact with pharmaceuticals, human or animal bodies and body fluids. Although tested for short term implantation, we do not recommend their use for implantation without further testing.

### Biomedical Grade

In addition to meeting all of the requirements of the USP VI Grade materials, Biomedical Grade silicone elastomers undergo additional biocompatibility testing including 90 day implantation. Each lot is screen strained to remove particulate contamination, and is subjected to a tissue culture testing.

Biomedical grades are suitable for use in the same applications as USP VI materials and for short term implantation (up to 29 days).

### Implantable Grade

Silicone grades suitable for long term implantation are also available. Each application must be approved by Precision Associates and the material manufacturer prior to purchase. Please contact PAI for additional information on Implantable Silicone Grades.



ISO 10993 is a series of standards for evaluating the effects of medical devices and their component materials on the body. Those commonly requested for rubber products are -5 (vitro cytotoxicity), -10 (irritation and skin sensitization), -11 (systemic toxicity).

Precision Associates' medical grade products are produced and packaged in our ISO 14644-1 Class 7 certified clean room. Although manufacture takes place in a clean room, it is not a sterile environment. Precision Associates medical grade materials may be sterilized by EtO, autoclave or gamma radiation.

Precision Associates does not guarantee fitness for use or any application. Purchaser is responsible for determining suitability of function. Certification is supplied with each shipment.



Toll Free: 1-800-394-6590

612-333-7464

FAX: 612-342-2417

[info@PrecisionAssoc.com](mailto:info@PrecisionAssoc.com)

3800 N Washington Ave, Mpls, MN 55412-2142

### USP VI / ISO 10993 Materials

	EPDM		Fluoroelastomer		
Durometer	Black	White	Orange	White	Black
70	423767	423725	48751	48725	48767

  

	Bromobutyl		Polyisoprene		Urethane	
Durometer	Cream		Cream		Clear	
40			41424 <sup>♦</sup>			
50	413524 <sup>♦</sup>		41524 <sup>*</sup>		435524	
75					435724	

### Dow Corning Platinum Cured HCR Silicone Compounds<sup>∞</sup>

Durometer	Base Material	Clear	White <sup>†</sup>	Black <sup>†</sup>	Red <sup>†</sup>	Blue <sup>†</sup>	Green <sup>†</sup>	Yellow <sup>†</sup>
15	MED-4014	49124	*	*	*	*	*	*
50	C6-135	49526	49525	49529	49559	49562	49523	49556
60	C6-150	49626	49625	49629	49659	49662	49623	49656
70	C6-165	49726	49725	49729	49759	49762	49723	49756
80	C6-180	49826	49825	49829	49859	49862	49823	49856

### Biomedical Grade Materials<sup>∞</sup>

#### Dow Corning Q7 Platinum Cured HCR Silicone Compounds

Durometer	Base Material	Clear	Red <sup>†</sup>	Black <sup>†</sup>	Blue <sup>†</sup>
40	Q7-4735	49470	49449	*	*
55	Q7-4750	49670	49549	*	*
75	Q7-4765	49770	49749	49767	*
80	Q7-4780	49870	49849	*	*

♦ Tested to meet ISO 10993-5. USP testing pending.

∞ Tested to meet ISO 10993-3/4/5/6/10/11

\* Contact Precision Associates for information on this formulation.

† Colored silicone compounds use applicable grade polymer and colorants tested to meet USP VI and ISO 10993.



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### Medical Grade/USP VI LSR Materials

Compounds listed below are Precision Associates standard materials and are typically in stock.

A wide selection of LSR polymers and colors are offered. Please inquire if a specific material is not listed as it may be available. Pantone color matching is also an option.

Duro	Base Material	Mfgr	Gray <sup>†</sup>	Clear	Blue <sup>†</sup>	Red <sup>†</sup>	White <sup>†</sup>	Orange <sup>†</sup>	Black <sup>†</sup>
30	LR 3003/30	Wacker		29306					
40	KEG-2000-40	ShinEtsu		29408			29411		
50	LIM 6050	Momentive	29505	29506	29517	29512		29510	29511
60	KEG-2000-60	ShinEtsu	29601	29602		29606	29607		
70	LIM 6071	Momentive	29705	29706					

### Long Term Implantable Grade/USP VI LSR Materials

Durometer	Base Material	Mfgr	Gray <sup>†</sup>	Clear	Blue <sup>†</sup>	Red <sup>†</sup>	White <sup>†</sup>
30	MED 4830	NuSil	29304	29303			
40	MED 4840	NuSil		29407			
50	MED 4850	NuSil		29514	29519		29518
60	MED 4860	NuSil			29605		
70	MED 4870	NuSil		29709			



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- ***Rubber Balls***
- ***Tri-Clamp Sanitary Gaskets***
- ***Medical Seals***
- ***Custom Molded Seals and Components***

- **ISO 13485:2016**
- **Custom Molding**
- **On-Site Mold Shop**

- **ISO 9001:2015**
- **Standard Seals**
- **ISO Class 7 Clean Room**

**Made in the U.S.A.**

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